510(k): k090266

510(k) SUMMARY
EyeIC's MatchedFlicker® Device

MAY - 6 2009

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Morris Waxler, Ph.D. President Waxler Regulatory Consultancy, LLC 1920 Arlington Place Madison, WI 53726-4002	Tel: 608-219-7547 No FAX number mwaxler@charter.net

Contact Person: Morris Waxler, Ph.D
Date Prepared: January 29, 2009

Name of Device and Name/Address of Sponsor

MatchedFlicker®

Ira Wallace, MD, MBA CEO EyeIC Corporation 231 Tower Lane Suite 200 Narbeth, PA 19072-1127	Phone 610-617-8957 Cell 610-331-5759 Fax 610-617-8883 iwallace@eyeic.com

Common or Usual Name: Digital Imaging Software

Classification Name: Picture Archiving & Communication System (21 CFR 892.2050. NFJ)

Predicate Devices

1. NAVIS by Nidek, Inc. (K013694)
2. Retasure by Digital Healthcare, Inc. (K071299),
3. IMAGEnet by Topcon Corp (K082364)

Intended Use:

The MatchedFlicker® device is a software program that is intended for use by health care professionals to collect, store, and spatially calibrate (i.e. register and align) images of the posterior segment of the human eye.

Technological Characteristics and Substantial Equivalence:

The MatchedFlicker® device is software to aid professionals to more easily compare and annotate time-series images of the posterior segment of the human eye for monitoring the progression of glaucoma and other diseases. Currently these analyses are performed by a side-by-side comparison of serial mono or stereo-photographs. For example, in glaucoma there are two challenges to assessing the structure of the optic nerve. The first is distinguishing between a normal and a glaucomatous optic nerve. Changes in retinal structure, which signal the advent and progression of retinal disease, can be seen in photographs much earlier than in visual field tests. The more important challenge is detecting glaucoma progression over time prior to visual field loss. The MatchedFlicker® device is an aid to photo-documentation of stereo evidence of glaucomatous (or other diseases') changes in the retina and other structures of the posterior segment over time.

MatchedFlicker® is digital imaging software regulated by FDA as a type of Picture Archiving and Communications System (21CFR 892.2050) under product code NFJ. It is substantially equivalent to other legally marketed digital imaging software. Specifically, EyeIC's MatchedFlicker® software is substantially equivalent to NAVIS manufactured by Nidek, Inc. (K013694), to Retasure manufactured by Digital Healthcare, Inc. (K071299), and to IMAGEnet manufactured by Topcon Corp (K082364).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2009

EyeIC, Corporation
c/o Morris Waxler, Ph.D.
Waxler Regulatory Consultancy, LLC
1920 Arlington Place
Madison, Wisconsin 53726

Re: K090266
Trade/Device Name: MatchedFlicker™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: April 6, 2009
Received: April 7, 2009

Dear Dr. Waxler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090266

Device Name: MatchedFlicker®

Indications for Use:

The MatchedFlicker™ device is a software program that is indicated for use by health care professionals to collect, store, and spatially calibrate (i.e. register and align) images of the posterior segment of the human eye.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NECESSARY0

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic & ENT Devices

510(k) Number K090266

Prescription Use X or Over-The-Counter Use _____
(Optional Format 1-2-96)